

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

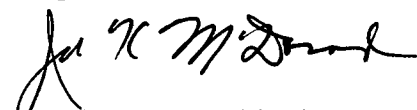
In re Application of: )  
)  
**JUAN JOSE LEGARDA IBANEZ** )  
)  
Serial No.: **10/622,068** ) Art Unit: **1614**  
)  
Filed: **July 15, 2003** ) Examiner: **Kim, Jennifer M.**  
)  
For: **Flumazenil for the Treatment of** )  
**Cocaine Dependency** )

COMMUNICATION

Mail Stop Issue Fee  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450  
Sir:

Pursuant to the attached copy of the Preliminary Amendment filed March 1, 2006, please amend the title of the above-identified patent application as follows: "~~Use of Flumazenil in the Production of a Medicament~~ for the Treatment of Cocaine Dependency". This change is also indicated on the Issue Fee Transmittal submitted herewith.

Respectfully submitted,



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Our Docket: 55979/314570 (0200)

## Certificate of Electronic Filing

I hereby certify that this correspondence is being electronically filed with The United States Patent Office via EFS Web, on December 20, 2006.

Lisa E. Norris: 

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: )  
)  
JUAN JOSE LEGARDA IBANEZ )  
) Art Unit: 1614  
Serial No. 10/622,068 )  
) Examiner: Not yet assigned  
Filed: July 15, 2003 )  
)  
For: Use of Flumazenil in the )  
Production of a Medicament for )  
the Treatment of Cocaine Dependency )

**PRELIMINARY AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Preliminary to any examination on the merits, Applicant respectfully submits the following amendments:

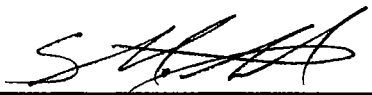
**Amendments to the Specification** begin on page 2 of this paper.

**Amendments to the Claims** are reflected in the listing of claims that begins on page 3 of this paper.

**Remarks** begin on page 5 of this paper.

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I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450, on March 1, 2006.

  
\_\_\_\_\_  
Stephen C. MacDonald, Ph.D. - Reg. No. L0063

**Amendments to the Specification:**

Amendments to the specification are presented below with replacement paragraphs marked up to show changes made relative to the immediate prior version.

Please replace the title of the application at page 1, lines 1 and 2 with the following amended title:

Flumazenil in the Production of a Medicament for the Treatment of Cocaine  
Dependency

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claims 1-18. (Cancelled)

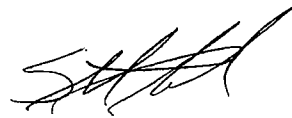
19. (New) A method for treating cocaine dependency, comprising administering a therapeutically effective amount of flumazenil to a patient in need of such treatment.
20. (New) The method of claim 19, wherein the flumazenil is administered sequentially at short time intervals in small quantities.
23. (New) The method of claim 19, wherein the flumazenil is administered at time intervals of between about one and about fifteen minutes.
24. (New) The method of claim 19, wherein the flumazenil is administered in quantities between about 0.1 and about 0.3 mg.
25. (New) The method of claim 19, wherein the flumazenil is administered at time intervals of between about one and about fifteen minutes in quantities between about 0.1 and about 0.3 mg.
26. (New) The method of claim 19, wherein the effective amount of flumazenil is between about 1.5 and about 2.5 mg/day.
27. (New) The method of claim 19, wherein about 0.2 mg of flumazenil is administered sequentially at intervals of about 3 minutes.
28. (New) The method of claim 19, wherein the flumazenil is administered orally or parenterally.
29. (New) The method of claim 28, wherein the parenteral administration of flumazenil is intravenous administration.
30. (New) The method of claim 19, wherein the flumazenil is administered before, during or after treatment with an additional agent.
31. (New) The method of claim 30, wherein the additional agent is clomethiazole.
32. (New) The method of claim 30, wherein the additional agent is selected from the group consisting of Vitamin B Complex, Piracetam, vitamins, minerals, proteins, amino acids, disulfiram, fluoxetine, and combinations thereof.

33. (New) The method of claim 19, wherein the flumazenil is administered under sedation.
34. (New) The method of claim 19, wherein the administration of flumazenil reduces or eliminates the desire to use cocaine.
35. (New) A method for treating cocaine dependency, comprising administering a therapeutically effective amount of flumazenil to a patient in need of such treatment, wherein the flumazenil is administered at time intervals of between about one and about fifteen minutes in quantities between about 0.1 and about 0.3 mg.
36. (New) The method of claim 35, wherein the effective amount of flumazenil is between about 1.5 and about 2.5 mg/day.
37. (New) The method of claim 35, wherein the administration of flumazenil reduces or eliminates the desire to use cocaine.

### Remarks

Upon entry of the present amendment, claims 19-37 will be pending in this application. Claims 1-18 have been cancelled without prejudice to the subject matter thereof, and claims 19-37 have been added to bring the claims in line with U.S. practice and to more clearly define certain aspects of the invention. Support for the new claims appears in the originally-filed translation of the specification at pages 4-6, 9-10 and 12. No new matter has been added.

Respectfully submitted,



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